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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,007	11/30/2005	Jan Grund-Pedersen	4145-000009/US	6870

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RESTON, VA 20195

EXAMINER

SAADAT, CAMERON

ART UNIT	PAPER NUMBER
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3715

MAIL DATE	DELIVERY MODE
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02/24/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,007	Applicant(s) GRUND-PEDERSEN, JAN	
	Examiner CAMERON SAADAT	Art Unit 3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/11/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/11/2010 has been entered. Claims 1, 3-10, and 12-16 are pending. Claims 2 and 11 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-10, and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (US 7,371,067) in view of Charbel et al. (US 7,191,110; hereinafter Charbel).

Regarding claims 1 and 7, Anderson discloses an interventional procedure simulation system and method, comprising a control unit and an interface unit, said control unit communicating with said interface unit to simulate handling of at least one instrument interfaced by said interface unit, wherein control unit comprises a database of vessels having a hierarchial structure (Col. 11, lines 48-61), each vessel having a diameter and a stiffness, and said instrument being a tool expandable in a simulated vessel, whereby when said tool is expanded, a geometry of said vessel changes resulting in a fluid flow change. See Col. 2, lines 28-45. Anderson discloses all of the claimed subject matter with the exception of disclosing the feature of recursively calculating the simulated fluid flow in *adjacent* simulated vessels. However, Charbel discloses a method of modeling circulation of vessels at any desired section in a circulating system including estimating flows under health and disease situations and as a result of treatment procedures. See Charbel, Col. 3, lines 17-27. Therefore, in view of Charbel, it would have been obvious to one of ordinary skill in the art to modify the vascular model described in Anderson by measuring blood flow dynamics in adjacent vessels in order to analyze the circulation system as a whole, rather than focusing on a single vessel location.

Regarding claim 3, Anderson discloses an instrument that is a balloon, stent and/or a distal protection tool. See Col. 2, lines 46-56.

Regarding claim 4, Anderson discloses that the vessel is realized by a tubular geometry and specific stiffness. See Fig. 5.

Regarding claim 5, Anderson discloses vessels that are realized by lesions having different stiffness than the neighboring vessel parts. See Col. 14, lines 33-63.

Regarding claim 6, Anderson discloses a system that calculates a flow through the hierarchal structure realized as a vessel-tree as a result of its geometry. (Col. 11, lines 48-61).

Regarding claims 8-10 Anderson discloses all of the claimed subject matter with the exception of disclosing that the flow simulation is modeled as an electrical resistive network. However, the examiner previously took official notice that the feature of modeling blood flow of a blood vessel in terms of resistance and current is old and well known, and therefore it would have been an obvious modification with predictable results to one of ordinary skill in the art. This position is supported by Charbel. Charbel discloses a method of modeling circulation using electrical network models, since these networks are good at simulating networks with capacitance and resistance. See Col.4, lines 31-44.

Regarding claims 12-13 and 16, Anderson discloses the feature of utilizing a real instrument. See Col. 20, lines 3-21 (the simulation system comprises a candidate medical device that interfaces with a manikin).

Regarding claims 14-15, Anderson discloses all of the features described in the rejection of claim 1 and additionally discloses the use of two instruments. See Col. See Col. 19, lines 39-44; Col. 20, line 66 – Col. 21, line 2; Col. 2, lines 46-56.

Response to Arguments

Applicant's arguments filed 1/11/2010 have been fully considered but they are not persuasive.

Applicant argues that Anderson does not calculate a flow through the combination of Anderson and Charbel does not teach or suggest an apparatus that is configured to recursively calculate a simulated flow change in the vasculature that results from changes in the geometry of a vessel during deployment of a medical device. The examiner disagrees. Anderson discloses all of the claimed subject matter with the exception of disclosing the feature of recursively calculating the simulated fluid flow in *adjacent* simulated vessels. However, Charbel discloses a method of modeling circulation of vessels at any desired section in a circulating system including estimating flows under health and disease situations and as a result of treatment procedures. See Charbel, Col. 3, lines 17-27. Therefore, in view of Charbel, it would have been obvious to one of ordinary skill in the art to modify the vascular model described in Anderson by measuring blood flow dynamics in adjacent vessels in order to analyze the circulation system as a whole, rather than focusing on a single vessel location.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CAMERON SAADAT whose telephone number is (571)272-4443. The examiner can normally be reached on 9:00-5:00 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cameron Saadat/
Primary Examiner, Art Unit 3715